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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,649	07/01/2003	Chris Rundfeldt	NY-HUBR 1221-US	2085
24972	7590	06/28/2006	EXAMINER	
FULBRIGHT & JAWORSKI, LLP				KANTAMneni, SHOBHA
666 FIFTH AVE				ART UNIT
NEW YORK, NY 10103-3198				PAPER NUMBER
				1617

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/611,649	RUNDFELDT ET AL.
	Examiner Shobha Kantamneni	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13, 15, 17, 18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-13, 15, 17, 18, 20, and 21 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. ____ .   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

## **DETAILED ACTION**

This Office Action is in response to the application filed on 07/01/2003. Claims 1-13, 15, 17-18, and 20-21 are pending.

Note that claims 15, 17, and 20 depend on canceled claims 14, 16, 19.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-3 (in part), 5-6 (in part), 8-12 (in part), 15 (in part), 17-18 (in part), 20-21 (in part), drawn to a method for the treatment of a skin disease comprising topically administering a compound of formula (I) or a pharmaceutically acceptable salt thereof, wherein R1 is C1-12-alkyl, straight-chain or branched-chain or -C2-C12 alkenyl, mono-or polyunsaturated as in claim 1, (i), and R5 is a mono-, bi- or tricyclic saturated or mono- or polyunsaturated carbocycle having 3-14 ring members, classified in class 514, subclass 763, 862.
- II Claim 1-3 (in part), 4 (in part), 6 (in part), 8-12 (in part), 13, 15 (in part), 17-18 (in part), 20-21 (in part), drawn to a method for the treatment of a skin disease comprising topically administering a compound of formula (I) or a pharmaceutically acceptable salt thereof, wherein R1 is C1-12-alkyl, straight-chain or branched-chain or -C2-C12 alkenyl, mono-or polyunsaturated as in claim 1, (i), and R5 is a mono-, bi- or tricyclic saturated or mono- or polyunsaturated heterocycle having 5-15 ring

members and 1-6 heteroatoms, classified in class 514, subclass 183, 277, 862.

- III Claim 1-3 (in part), 8-12 (in part), 15 (in part), 17-18 (in part), 20-21 (in part), drawn to a method for the treatment of a skin disease comprising topically administering a compound of formula (I) or a pharmaceutically acceptable salt thereof, wherein R1 is C1-12-alkyl, straight-chain or branched-chain or –C2-C12 alkenyl, mono-or polyunsaturated as in claim 1, (i), and R5 is a carbo-or heterocyclic saturated or mono-or polyunsaturated spirocycle having 3-10 ring members, classified in class 514, subclass 212.02, 278, 766, 862.
- IV Claim 1-3 (in part), 7-12 (in part), 15 (in part), 17-18 (in part), 20-21 (in part), drawn to a method for the treatment of a skin disease comprising topically administering a compound of formula (I) or a pharmaceutically acceptable salt thereof, wherein R1 is as in claim 1, (ii), and R5 is a mono-, bi- or tricyclic saturated or mono- or polyunsaturated carbocycle having 3-14 ring members, classified in class 514, subclass 763, 862.
- V Claim 1-3 (in part), 7-12 (in part), 15 (in part), 17-18 (in part), 20-21 (in part), drawn to a method for the treatment of a skin disease comprising topically administering a compound of formula (I) or a pharmaceutically acceptable salt thereof, wherein R1 is as in claim 1, (ii), and R5 is a mono-, bi- or tricyclic saturated or mono- or polyunsaturated heterocycle having

5-15 ring members and 1-6 heteroatoms, classified in class 514, subclass 183, 277, 862.

VI      Claim 1-3 (in part), 7-12 (in part), 15 (in part), 17-18 (in part), 20-21 (in part),, drawn to a method for the treatment of a skin disease comprising topically administering a compound of formula (I) or a pharmaceutically acceptable salt thereof, wherein R1 is as in claim 1, (ii), and R5 is a carbocyclic or heterocyclic saturated or mono-or polyunsaturated spirocycle having 3-10 ring members, classified in class 514, subclass 212.02, 278, 766, 862.

Inventions I-VI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the inventions are separate and distinct each from the other because the compounds of Groups I-VI differ by a significant structural feature, having different formula, which are classified in different subclass of class 514, for example the compound of formula (I), wherein R5 is pyridine is classified in subclass 277, and the compounds of formula (I), wherein R5 is a carbocycle classified in subclass 763.

Given the fact that chemical compounds that are not similar in structure have different physical, chemical, biological and physiological properties or activities, the instant compounds are deemed to have different modes of operation, different functions, and different effects.

Moreover, the search for inventions of Groups would place an undue burden on the Office because of their separate classification crossing class 514. It is noted that for example a reference to one indole compound of formula (I), wherein R1 is C1-12 alkyl group would not be a reference to another indole compound of formula (I), wherein R1 is a polyunsaturated carbocyclic group, under 35 U.S.C. 103(a).

The above inventions differ as distinct therapeutic methods.. The grouped inventions are patentably distinct, a reference which would anticipate, or make obvious, any inventions from groups I-VI would not necessarily obviate or anticipate, the inventions in any other group. The searches are not co-extensive as indicated by the diverse nature of the subject matter. The search for all inventions would place an undue burden on the office in view of the diversity of the compounds involved in the treatment methods and the corresponding diversity in the field of search for each. Note that the search involves both patent and non-patent literature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one or more

claim remaining in the application. Any amendment of inventorship must be accompanied by request under 37 CFR 1.48(b) and by fee required under 37 CFR 1.17(i).

*Election of Species*

This application contains claims directed to patentably distinct species of the claimed invention:

- 1) A single disclosed species, a compound of formula (I).

If applicant elects any of groups I-VI, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed compound of formula (I) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-12, 15, 17-18, 20-21 are generic to a plurality of compounds.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call to the applicant's agent to request an oral election was not made, due to the complexity of the restriction.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Shobha Kantamneni  
Patent Examiner  
Art Unit : 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER